EPF RESPONSE TO THE OPEN CONSULTATION ON PATIENT SAFETY IN THE EUROPEAN UNION

20 May 2008

This document presents EPF’s response to the online questionnaire on patient safety in the EU: http://ec.europa.eu/health/ph_overview/patient_safety/consultation_en.htm.

The European Patients’ Forum (EPF) was founded in 2003 to become the collective patients’ voice at EU level, manifesting the solidarity, power and unity of the EU patients’ movement. EPF currently represents 35 member organizations – which are chronic disease specific patients organizations operating at European level, and national coalitions of patients organisations. EPF reflects the voice of an estimated 150 million patients affected by various diseases in the European Union, and their families.

EPF facilitates the exchange of good practices and challenging of bad practice on patients’ rights, equitable access to treatment and care, and health-related quality of life between patient organizations at European level and at Member States level. Developing knowledge on the needs and interests of patients, from a patient perspective, is only possible with the active involvement of patients and/or patient representatives.

2. National Political Support for Patient Safety

If patient safety needs to be improved in EU Member States, a culture of patient safety is surely desirable at all levels. A clear political desire to reduce the level of harm to patients will hopefully positively influence patient safety cultures and actions throughout the healthcare system by sending the right signals as to its importance to the delivery of good quality healthcare.

QUESTION 8
How important would a national commitment to improving patient safety in your country be?

Very important

QUESTION 9
How important would a national patient safety strategy in your country, (perhaps as part of a general healthcare quality strategy) be?

Very important
QUESTION 10
How important is it to have an EU strategy for patient safety?

Very important

QUESTION 11
What types of adverse events do you think competent authorities in your country should be prioritising in their efforts? In order of importance, please rank the following from 1-7, 1 being the highest priority in your opinion:

- medication-related event
- medical device or equipment-related event
- healthcare-associated infection
- error in diagnosis surgery-related event
- communication problems
- others (please specify)

All these adverse events are important from a systemic approach.

QUESTION 12
What do you think should be the essential components of a patient safety strategy in your country or the patient safety elements of a healthcare quality strategy? Please rank the following from 1-10, 1 being the most important in your opinion:

- political leadership and financial support?
- a reporting and learning system
- patient involvement in policy development
- health professional involvement in policy development
- patient safety education for health professionals
- standards and/or external assessment for patient safety
- patient safety indicators
- a dedicated patient safety research agenda and budget
- a compensation system for those harmed by healthcare (or their families)
- other (please specify)

All these components are important in a coherent patient safety strategy.

3. Budgetary Commitment to Safety

Whilst high level political support to improve the safety of patients is desirable, many patient safety policies, strategies and systems will also incur a financial cost. It is, therefore, perhaps important that dedicated financial resources are identified at the national and local levels to support patient safety initiatives.

QUESTION 13
How important is it to have a dedicated national resource commitment for patient safety initiatives in your country?
Very important

**QUESTION 14**
How important is it to have resources identified at the healthcare organisation level for patient safety initiatives in your country?

Very Important

**QUESTION 15**
How important is it to have dedicated resources at the EU level to support Member States in addressing patient safety concerns?

Very important

### 4. Patient and Public Involvement in Patient Safety Improvements

When things go wrong in healthcare systems, it is the patients and consumers of that system who are the primary sufferers from any harm caused, including physical injury, psychological damage, or financial damages. Some may feel that it is important that the experiences and perspectives of these groups are taken into account to efforts to improve the safety of patients.

Patients can often provide a personal and unique insight into safety issues in healthcare systems. Those experiences can be used to reduce the levels of unsafe care and handle situations where patients have suffered harm from healthcare much more satisfactorily. Patient and public involvement in the area of patient safety could be an important part of better patient-centered care.

**QUESTION 16**
How important is it that patients should be seen as experts on patient safety in your country?

Very important

**QUESTION 17**
How important is it that patients should not just informed but also empowered to take part in patient safety and quality programme in your country?

Very important

**QUESTION 18**
How important is it to have systems in place at national and local level to involve patient groups?

Very important

**QUESTION 19**
How important is it that patients and the public should be informed about potential and actual patient safety incidents and adverse events in your country?

Very important

**QUESTION 20**
How important is it that patients (and/or their families) should be suitably supported in the aftermath of a patient safety incident?

Very important

**QUESTION 21**
What further action, if any, would you like to see in your country to improve the involvement of the patient or public in patient safety policies and programmes?

N/A

5. Local Healthcare Management and Leadership

At the local level, it may be desirable that all individual healthcare organisations – i.e. the providers of care - place safety at the centre of their organisational cultures and quality of care strategies and communicate its importance to staff and patients. A positive safety culture might possibly enable health professionals to be more open, accept errors as part of the process of delivering healthcare and allow investigation of error without blame.

**QUESTION 22**
How important is it that patient safety is treated seriously by the management of healthcare organisations in your country?

Very important

**QUESTION 23**
How important is it for healthcare providers to have effective and comprehensive communications systems on patient safety issues and concerns in place?

Very important

**QUESTION 24**
How important is it for every healthcare provider to have a senior person responsible for the safety of patients?

Very important
6. Health Professionals

Even if good national and healthcare provider patient safety cultures exist, some may argue that the safety of patients will not be optimised unless individual healthcare professionals are aware of the importance of the safety of their patients and steps they can take in their everyday practice to reduce the risk of harm to those patients. Whether patient safety is adequately embedded into the education, training and continuing professional development of those health professionals will vary from organisation to organisation and from country to country. It is also important that health professionals are appropriately regulated and competent to practise if patients are to be safe-guarded. Health professionals achieving fitness to practise status would suggest that patient safety is not being unduly compromised by their actions and behaviours. Good systems of professional regulation should hopefully pick up 'high' risk practice, behaviours or attitudes.

**QUESTION 25**
How important would further educating health professionals in your country in the area of patient safety be in reducing adverse events?

Very important

**QUESTION 26**
How important would including patient safety in the continuing professional development of health professionals in your country be in reducing adverse events?

Very important

**QUESTION 27**
How important are systems regulating health professionals, including disciplinary procedures, in efforts to minimise unsafe care in your country?

N/A

**QUESTION 28**
How important are professional standards and codes of practice for health professionals in efforts to minimise unsafe care in your country?

Very important

**QUESTION 29**
How important is it for health professionals to be suitably supported in the aftermath of a patient safety incident?

Very important

**QUESTION 30**
What further action, if any, do you think needs to be taken to improve the knowledge and awareness of patient safety issues and increase the application of safer practice actions among health professionals in your country?

N/A

7. Reporting and Learning Systems

The primary objective of patient safety reporting systems is to enhance patient safety by learning from failures of the healthcare system. It could be argued that reporting in itself is of limited value. The information gathered through such systems, however, could be analysed, disseminated and used to implement changes that might lead to safer care in the future. It is important that those reporting problems using such systems do not suffer in any way as a result of that reporting.

QUESTION 31
How important is it for there to be a national reporting and learning system that collects, analyses and monitors information on adverse events and patient safety incidents in your country?

Very important

QUESTION 32
How important is it for incident and adverse event data and the results of analyses to be evaluated and shared nationally in your country, without being used to discipline individuals?

Very important

QUESTION 33
How important is it for there to be a national (or regional) organisation (institute, agency etc) that actively seeks out and tries to spread best practice and learning in your country?

Very important

QUESTION 34
How important is it for the data from national (or regional) reporting and learning systems to be pooled at the EU level as a common resource for learning?

Very important

8. Other Patient Safety Information and the Sharing of Information

As highlighted in Section 6, it may be considered by some that the number, types, causes and consequences of errors and adverse events should be shared. Currently, however, intra- and inter-country comparisons could possibly be being hindered by the lack of a common patient safety classification or terminology. A common classification system could elicit,
capture and analyse factors relevant to patient safety in a manner conducive to learning and system improvement, in an adaptable yet consistent way. Currently, there is a multiplicity of terms and definitions in use in the EU for the key aspects of patient safety including, for example, 'harm', a 'patient safety incident', an 'adverse event' and 'medical error'. Language difficulties may exacerbate this problem.

Patient safety indicators - administrative data-based indicators which identify potential safety events - may be a useful tool in identifying the extent and type of some of the major patient safety incidents as well as for examining trends over time. However, again both intra- and inter-country comparisons may suffer from the absence of a standard set of patient safety indicators. It may also be more difficult to evaluate the impact of actions on patient safety without a standard set of indicators.

**QUESTION 35**
How important is it for there to be a common patient safety classification or terminology system in your country?

Very important

**QUESTION 36**
How important is it for common classification or terminology system to be developed and used throughout the European Union?

Very important

**QUESTION 37**
How important is it for a common set of patient safety indicators to exist in your country?

Very important

**QUESTION 38**
How important is it for a common set of patient safety indicators to be developed and used throughout the European Union?

Very important

**9. Standards and/or External Assessment**

It could be argued that the use of a set of minimum standards for patient safety would help to drive up patient safety levels in all healthcare organisations. Compliance with such standards could support performance improvement in healthcare. Some people working in the area of patient safety advocate the use of a system of external assessment for patient safety, which could be used to certify that healthcare organisations have complied with a set of patient safety criteria, perhaps in the form of required minimum standards for patient safety, as a key risk reduction tool. Systems of external assessment and standards could operate in isolation or with one underpinning the other and may or may not involve some form of accreditation.
QUESTION 39
How important is it for there to be a system of minimum patient safety standards for healthcare organisations in place in your country?

Very important

QUESTION 40
How important is it for there to be a common set of minimum standards for patient safety for all healthcare organisations within the EU?

Very important

QUESTION 41
How important is it for there to be a system of external assessment of healthcare organisations in respect of patient safety in your country?

Very important

QUESTION 42
How important is it for there to be a common system of external assessment for all healthcare organisations in the EU in respect of patient safety?

Very important

QUESTION 43
If your response to Question 39 is in favour of a system of minimum patient safety standards, which organisation(s) do you think should be responsible for setting and monitoring performance against these standards in your country?

EPF believes that an independent body should be responsible for setting and monitoring performance against safety standards, with a well-defined set of quality criteria standards and an ongoing monitoring approach. We also call for consultation with all stakeholders and for a meaningful involvement of patients’ representatives in this process.

QUESTION 44
If your response to Question 40 is in favour of a system of external assessment for patient safety, which organisation(s) do you think should be responsible for carrying out such an assessment in your country?

An independent agency with a Board including all stakeholders’ members should carry out such an assessment. EPF calls for an independent and transparent evaluation process.
10. Research and Development around Patient Safety

Patient safety research (basic and applied) is taking place in the European Union and elsewhere in the world on the nature, number and causes of patient safety incidents, as well as into possible patient safety solutions and interventions. The results of that research may be vital to inform the policy-makers and those involved in the delivery of healthcare, especially research which identifies the causes of incidents and harm and effective solutions. However, some argue that there are still many gaps in the research, and that results of patient safety research are not always disseminated widely, either within countries or among other EU countries.

QUESTION 45
How important is it for resources to be allocated to patient safety research in your country?

Very important

QUESTION 46
How important is increased co-operation between EU Member States, supported by the European Community, on the priority-setting, and the commissioning, of patient safety research?

Very important

QUESTION 47
How important would a database at the EU level be, which would bring together results of patient safety research and other learning and experiences, to be used as a common European resource?

Very important

QUESTION 48
How important are I.T tools aimed at providing health professionals with relevant, timely and up-to-date information, such as comprehensive electronic health records, decision support systems, e-prescription support and IT-based surgery training, to efforts to reduce harm?

Very important

QUESTION 49
In which areas of patient safety do you think more research needs to take place, if any? Possible areas include research on the extent of harm, the type of harm, on patient safety interventions, on the economic costs of harm, on harm outside the hospital setting and any others you feel are currently under-researched.

Our starting point is that patients should be involved in setting the research agenda on patient safety from the very onset. Patients have a unique expertise and knowledge and they can contribute in identifying, from a patients perspective,
important issues regarding patients’ safety, and setting priorities for research. These priorities may sometimes differ from those of researchers and may also be complementary. With the right support, patients’ organizations can play a critical role in participating in research as well as in disseminating the results through their networks and facilitating the dialogue between researchers and policy-makers. From this perspective, the Conclusions and the ten-point Call for Action of the Patient Safety Research Conference – Shaping the European Agenda (24-26 September 2007), are extremely relevant: one key recommendation has been indeed to develop strategies to involve patients in patient safety research programmes and activities. 

http://www.patientsafetyresearch.org/psnews.htm/

Furthermore, there is a need for a more systematic European intelligence work and research on what patients from different disease areas define as priorities in patients’ safety.

Patients’ view on health literacy (skills, understanding, access and use of information, opportunity to share the decision-making) in relation to patient safety and quality of healthcare should be taken also on board.

QUESTION 50
If you answered positively to Question 47 (How important would a database at the EU level be, which would bring together results of patient safety research and other learning and experiences, to be used as a common European resource?) what type of information should be held centrally?

EPF strongly supports the project of a database at EU level to be used as a common European resource. This would facilitate sharing good practices, prevention strategies, lessons learned, specific actions to improve patients’ safety and quality of the healthcare, research results and learning interventions. It would also help establishing positive comparisons between countries. We strongly call for an accessible, easy to navigate system, with high-quality information that can be accessed and used by patients and patients’ organizations.

QUESTION 51
Again, if you answered positively to question 47, who or which organisation should be responsible for maintaining the central mechanism?

This organization responsible for maintaining the central system should be a recognized independent body.

11. Complaints and Redress

Whilst many measures can be taken to reduce the number of patient safety incidents and harm to patients in EU Member States’ healthcare systems, it should be acknowledged that because the science of medicine carries with it a degree of risk, and healthcare is delivered
in a complex environment, some patients will inevitably be harmed through the process of healthcare.

It could be argued that systems should be in place at the local and national levels to deal with these cases where things have gone wrong and patients have been harmed. Redress can be through financial (payment to compensate for harm, to pay for rehabilitation, loss of earnings etc) or non-financial (acknowledgments of error, explanations, apologies, reassurances that systems and processes will be changed to prevent re-occurrence and that fair and objective regulatory and/or disciplinary action will be taken etc) mechanisms or a combination of the two.

QUESTION 52
How important is for there to be an arbitration system for settling complaints without going to court in your country?

Very important

QUESTION 53
How important is it for patients to have access to available information on the redress available to them if they (or their families) are harmed by healthcare in your country or in other EU countries?

Very important

QUESTION 54
How important is it for the system of redress in your country to be based on the ability of the patient to prove an error was made by one or more healthcare professionals?

Very important

QUESTION 55
How important is it for there to be a national-wide system for calculating compensation payments in your country?

Very important

QUESTION 56
How important is it for compensation systems in your country to cover not only physical harm but other factors such as loss of income?

Very important

QUESTION 57
How important would it be to have an EU-wide system of redress?

Very important
12. General Issues

QUESTION 58
Adequate steps are being taken in your country to tackle the problem of patient safety

N/A

QUESTION 59
The European Community can play a role in supporting Member States in their efforts to address patient safety concerns

Strongly agree

QUESTION 60
What (further) action needs to take place in your country at the national, regional and/or local levels to improve patient safety?

We call for a strong political commitment from governments and authorities both individually and collectively to provide the resources to improving the quality of health care and patients’ safety across EU. We also want explicit, measurable and well defined indicators for this to really happen in practice.

We urge for a partnership between all institutions involved in patient safety, in a “no shame no blame” culture, based on trust and values and for a meaningful involvement of patients organizations.

QUESTION 61
In which areas of patient safety should the European Community play a role in supporting Member States in their efforts to address patient safety concerns and how should this support work in practice?

The European Community has a crucial role to play in supporting Member States in addressing patient safety concerns at national, regional and local level and in coordinating activities. There are valuable good practices in Member States that need to be shared. The European Community can also play a role in coordinating and setting standards for reporting. Moreover, there is a need for setting up a European system that is able to deal with redress of all types of patients.

EPF strongly calls for a European approach to tackling the challenges of preventing avoidable adverse events, which is value-based and ethics-driven.

To ensure coherence and follow-up, EPF would strongly recommend that the following documents are referred to, distinguishing and encouraging the EU’s role and Member States’ role:

- Luxembourg Declaration on patient safety – Patient safety make it happen (2005),
• World Health Organization “Quality of care”: patient safety” Resolution (WHA55, 18 May 2002)
• Council of Europe Recommendation Rec. (2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care.